IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Neeraj Kohli, M.D., M.B.A.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Exclude the General Causation Opinions of Neeraj Kohli, M.D., M.B.A. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4817]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, BSC's Motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, http://www.wvsd.uscourts.gov/MDL/boston/orders.html. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v.*

Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We

agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Kohli is a practicing urogynecologist who is board-certified in both Obstetrics-Gynecology and Female Pelvic Medicine and Reconstructive Surgery. He has nearly twenty years of experience and has authored more than one hundred scientific papers in the field of urogynecology. He has also served as a clinical consultant and educator for various medical products companies.

A. Properties of Polypropylene Mesh

First, BSC argues that Dr. Kohli's opinions on the properties of polypropylene mesh should be excluded because they are unreliable and he is unqualified to offer them. Specifically, Dr. Kohli seeks to offer opinions on chronic inflammation,

scarring/shrinkage/contraction, foreign body reactions, fibrosis, nerve entrapment, deformation, and degradation.

Regarding his qualifications, BSC claims that Dr. Kohli "has no formal education or training in material science, biomedical engineering, or polymers." Dr. Kohli is an experienced urogynecologist, and he has performed many surgeries implanting and removing polypropylene mesh devices used for the treatment of SUI. I have generally found that such experience qualifies physicians to opine on the properties of polypropylene irrespective of a lack of specialized knowledge of biomaterials. I likewise find that Dr. Kohli's experience with polypropylene mesh devices sufficiently qualifies him to offer opinions regarding foreign body reaction, shrinkage, and degradation. BSC's Motion as to this point is **DENIED**.

Next, BSC argues that Dr. Kohli's opinions on the properties of polypropylene mesh are unreliable because 1) they are not generally accepted in the medical community, 2) he has conducted no testing to support his theories, and 3) they are based on an inadequate selection of scientific literature. BSC claims that Dr. Kohli's opinions are contrary to the position statements of the American Urogynecological Society ("AUGS") and that they "fall on the extreme fringe of his profession." Mot. to Exclude 8. I disagree. Dr. Kohli cites to numerous medical articles in support of his opinions, which shows that he is not "on the extreme fringe of his profession." To the extent that his opinions are subject to disagreement within the medical community, this can be addressed on cross-examination. BSC's Motion on this point is **DENIED**.

B. Product Design

Second, BSC argues that Dr. Kohli's opinions on product design/design defect are irrelevant and that he is unqualified to offer them. Specifically, Dr. Kohli seeks to offer the opinion that the surgical insertion and fixation methods of the Pinnacle and Obtryx devices render the devices defective in design, and suggests other surgical procedures with other products as a "safer alternative design."

Regarding his qualifications, BSC argues that Dr. Kohli lacks experience in designing mesh products. I disagree. Dr. Kohli has served as a clinical consultant and educator for various medical products companies. He currently serves as Chief Medical Officer for the medical device company Emmy Medical. In that role, he has experience with material safety standards and Directions for Use ("DFU"). Therefore, I find that Dr. Kohli is qualified to testify regarding product design. BSC's Motion on this point is **DENIED**.

Next, BSC argues that Dr. Kohli's opinions regarding a safer alternative design are irrelevant because alternative products or alternative surgical methods do not constitute evidence of a reasonable alternative design to the product at issue. The relevance of these opinions are best addressed on a case-by-case basis. Therefore I **RESERVE** ruling on this issue.

C. Complication Rates

Third, BSC seeks to exclude Dr. Kohli's opinions that the Pinnacle and Obtryx devices have "an unacceptably high rate of mesh exposure/erosion, dyspareunia, and chronic pain complications," and that "the Pinnacle mesh causes an unreasonable

risk or severe and permanent injuries to women." Kohli Report for Donna Palmer 5. BSC argues that these opinions are unreliable because Dr. Kohli does not provide any basis to support them. I agree. Dr. Kohli offers no scientific support or methodology for opining on what constitutes an "unacceptably high" complication rate. The unreliability of Dr. Kohli's opinion is highlighted by the fact that he does not even opine on what the actual complication rates are. Instead, he asserts that, whatever the rate, it is unacceptably high. Therefore, Dr. Kohli's opinions on complication rates are **EXCLUDED**. BSC's Motion on this point is **GRANTED**.

D. Adequacy of Warnings

Fourth, BSC argues that that Dr. Kohli is unqualified to opine on the adequacy of the mesh device DFUs because he "is not a warnings expert, nor is he an expert in the FDA regulatory framework for the approval of medical devices." Mot. to Exclude 12. I disagree. As discussed above, Dr. Kohli has served as a clinical consultant and educator for various medical products companies. He currently serves as Chief Medical Officer for the medical device company Emmy Medical, and has experience with material safety standards and FDA regulations for medical devices. Additionally, he has previously drafted and approved DFUs. Therefore, I find that Dr. Kohli is qualified to opine on the adequacy or inadequacy of the DFUs. BSC's Motion on this point is **DENIED**.

E. Legal Conclusions

Finally, BSC contends that Dr. Kohli seeks to offer testimony constituting various legal opinions. Specifically, BSC points to Dr. Kohli's opinion that the "risks

of the BSC Pinnacle/Obtryx outweigh its benefits." Kohli Report for Donna Palmer 6; Kohli Report for Debra Ross 15. This opinion does not constitute a legal conclusion. It does not use any legal terms of art, and it does not answer a question that is strictly within the province of the jury. Accordingly, BSC's Motion on this point is **DENIED**.

IV. Conclusion

To summarize, BSC's *Daubert* Motion concerning Dr. Kohli [ECF No. 4817] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation